EXHIBIT E1

SUPERIOR COURT OF THE DISTRICT OF COLUMBIA

CIVIL DIVISION

LORI OULES,	)	
	)	Judge Brian Holeman
Plaintiff,	)	Civil Action No.
	)	2014 CA 088327 B
vs.	)	
	)	
JOHNSON & JOHNSON, et al.,	)	
	)	
Defendants.	)	

--- This is the continued transcript of the deposition of JACK SIEMIATYCKI, Ph.D, taken at 850 St. Denis Street, Montreal, Quebec, on the 16th day of December, 2016.

REPORTED BY: HELEN MARTINEAU

CERTIFIED SHORTHAND REPORTER

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your article --
MS. PARFITT: Is this a different question?
BY MR. HEGARTY:
Q. This is a different question. The Hartge paper that you list in your article did not find a statistically significant increase in relative risk between talc use and ovarian cancer, correct?
A. At the .05 P-value level.
Q. Whittemore did not find a statistically significant increase in relative risk at the .05 level, correct?
A. Correct.
Q. Booth did not find a statistically significant increase in risk, correct?
A. That's correct.
Q. Rosenblatt did not find a statistically significant increase in risk, correct?
A. Correct.
Q. Tzanou did not find a statistically significant increase in risk?
A. That's correct.

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Q. The Wong paper did not find a statistically significant increase in risk?
A. That's correct.
Q. And when a meta-analysis was done of those six studies it came to a relative risk of 1.12, that was not statistically significant at the .05 confidence interval, correct?
A. That's correct.
Q. Then in that paper you compared those groups of studies to the population-based, case-control studies and you did a test for heterogeneity, correct?
A. That's correct.
Q. And you found there was heterogeneity between the population-based cased, case-control studies and the hospital-based, case-control studies, correct?
A. Correct. Just a small correction, when you say, when did this or when you found this, the "you" refers to the collective authorship group and not to me personally because I didn't carry out any of these analyses personally. Is that understood?
Q. Did you disagree with the analyses?

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A. You know, this is ten years old the work on this; and I can't remember whether I disagreed or expressed any disagreement with particular tactics in the analysis strategy of this thing.
Looking at it now I would not choose to focus on the distinction between hospital-based and population-based studies the way this article presents it. Because, as I stated in my report, I think the quality of a study depends on many factors, of which whether it's hospital-based or population-based is only one. And, furthermore, the general opinion among epidemiologists, as one would see in textbooks, is that generally population-based studies are superior to hospital-based studies, but I don't ascribe to that as a strong motivating factor for judging the quality of individual studies.
Q. In fact, nowhere in your paper -- I'm sorry, nowhere in your report do you say that population-based, case-control studies are superior to hospital-based, case-control studies, correct?
A. That's correct.

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Q. You've never said that in any published article, correct?
A. Not that I recall.
Q. Now, in the Langseth paper the authors chose to divide up the forest plot between the population-based, case-control studies and the hospital-based, case-control studies, correct?
A. Yes.
Q. Did you disagree with that division of the forest plot back at the time that this article was prepared?
A. I can't answer that question. I just can't remember.
Q. Do you have any documents remaining from your exchange of drafts with regard to preparation of the Langseth paper back in 2006, 2007, 2008?
MS. PARFITT: Objection, form.
THE DEPONENT: I've no idea. I doubt it.
BY MR. HEGARTY:
Q. The test for heterogeneity with regard to hospital-based and the population-based, case-control studies show that the two groups of

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studies were different, correct?
A. That the results were different, that on average the ORs were different, yes.
Q. That means in -- I'll probably get this wrong, but the confidence intervals as they were overlapping were different, correct?
A. Well, you can see how the confidence intervals overlap just by looking at it. So it's not quite -- the overlap of the confidence intervals isn't a perfect gauge of whether two estimates are significantly -- statistically significantly different from each other but they are -- it is a good rough guide. And where it says that the heterogeneity test between groups was with a P .036 that would -- I have no reason to doubt the validity of that estimate, even though it wasn't me who derived it.
That would indicate that the difference between those estimates, the 1.40 for a population-based studies and 1.12, with their respective confidence intervals, were statistically significantly different at certain P value.
Q. Correct. With regard to the studies

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that have looked at talc use and ovarian cancer we have the three cohort studies, correct?
A. Right.
Q. We have six hospital-based, case-control studies as reported in the Langseth paper, correct?
MR. ABNEY: Object to form.
BY MR. HEGARTY:
Q. Let me say that differently. We have hospital-based, case-control studies that looked at talc and ovarian cancer, correct?
A. Correct.
Q. We also have population-based, case-control studies that looked at talc and ovarian cancer, correct?
MS. PARFITT: Not just in the Langseth but overall, Mark?
BY MR. HEGARTY:
Q. Overall.
A. Can I make a comment again about terminology? We're debating about "hospital-based" and "population-based" studies. There is some confusion about the terminology of what those things mean. And I'm not trying to be

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coy about this but in the Langseth paper it was, I think, a somewhat cavalier distinction was made; but you can have population-based case series, you can have hospital-based case series, you can have population-based controls, and you can have hospital-based controls, and you can have combinations of. So it's possible for a study to have one type of case series, population or hospital-based, and one type of control series, hospital or population-based, and different ones of each; and how these are labelled as being a population-based study or a hospital-based study is unclear. There are no clear guidelines for how those terms should be used.
I prefer myself now, as I come to recognize this terminological problem, to refer to hospital-based or population-base case series and hospital-based or population-based control series.
I only say this to indicate that when we're making -- when this report and other publications are commenting on hospital-based versus population-based studies it's not clear exactly what is being compared and what is being lumped together.

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Q. With regard to the epidemiologic studies that have looked at talc and ovarian cancer, we have the cohort studies and those cohort studies uniformly showed nonstatistically significant results, correct?
MS. PARFITT: Objection, form.
THE DEPONENT: The three that you mention, yes.
MS. PARFITT: For all types.
BY MR. HEGARTY:
Q. And with regard to the hospital-based, case-control studies --
A. Nurses' Health Study in the Gates' 2008 report did indicate -- sorry, a nonstatistically significant result, yes.
Q. And we the hospital-based, case-control studies that we just looked at in the Langseth paper, and those showed uniformly non-statistically significant results, correct?
A. Individually they showed non-statistically significant results.
Q. And combined in a meta-analysis they showed a non-statistically significant result?
A. That's correct.

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Q. With regard to population-based, case-control studies when those combined they showed an statistically significant increase in relative risk, correct?
A. Correct.
Q. But within those particular studies themselves they were mixed with regard to individual studies being statistically significant or not, correct?
MS. PARFITT: Objection, form.
THE DEPONENT: You mean some of the individual studies were and some were not?
BY MR. HEGARTY:
Q. Correct.
A. Is that what you're saying? Yes.
Q. And with regard to Hill, do you have the Hill paper handy? Under his section on consistency that begins on page 8, that is Exhibit 20, and carries over to page 9, at the top of page 9.
A. Sorry.
Q. Sorry, page 297.
A. So 297.
Q. Yes, the very bottom paragraph.

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A. Left-hand sides.
Q. Sorry, on page 296. This paragraph read:
"We have, therefore, the somewhat paradoxical position that the different results of a different inquiry certainly cannot be held to refute the original evidence. Yet the same results from precisely the same form of inquiry will not invariably greatly strengthen the original evidence. I would myself put a great deal of weight upon similar results reached in quite different ways. For example, prospectively and retrospectively."
Do you see where I'm reading?
A. Yes, I do.
Q. Now, with regard to the prospective studies that looked at talc and ovarian cancer, as we discussed those show a uniform, non-statistically significant result, correct?
MS. PARFITT: Objection, form.
THE DEPONENT: What they show is a series of odds ratio estimates and their

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confidence intervals. What the statistical significance is interpretation. So there's what the data shows and then there is interpretation of what the data shows.
BY MR. HEGARTY:
Q. Well, the cohort studies individually did not show an association between talc use and ovarian cancer, correct?
MS. PARFITT: Objection, form.
THE DEPONENT: They showed odds ratios with confidence intervals is what the data of those studies showed.
BY MR. HEGARTY:
Q. Those studies did not show an association between talc use and ovarian cancer, correct?
MS. PARFITT: Objection, form.
THE DEPONENT: They showed, again, as an example a result like -- if we go to the Langseth forest plot --
BY MR. HEGARTY:
Q. Doctor, I'm talking about the cohort studies.
MS. PARFITT: Let him finish.

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MR. HEGARTY: He's not answering my question.
MS. PARFITT: Maybe he is. Do you understand his question?
BY MR. HEGARTY:
Q. Do you understand my question?
A. The cohort studies only.
Q. The cohort study only. The cohort studies individually did not show an association between talc use and ovarian cancer?
MS. PARFITT: Objection, form.
THE DEPONENT: So the Gates' reports, the Gates publications, the two of them, and the Nurses' Health Study report -- if we look at all tumors they --
BY MR. HEGARTY:
Q. Doctor, I'm not asking for the relative risk.
MS. PARFITT: Excuse me, let him finish please.
THE DEPONENT: But the relative risk is what they show.
MS. PARFITT: Complete your answer.
THE DEPONENT: The statistical

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significance is an interpretation of what they show based on a judgment of what level of statistical proof you want to have before you reject the null hypothesis. That's opinion.

There's what the data shows and then you layer opinion over that data. What it shows is the odds ratios, relative risks and the confidence intervals. That gets interpreted as statistical significant by the person who is interpreting it based on their -- the P values that they think are relevant.

BY MR. HEGARTY:

Q. Well, let me ask a different question. The prospective studies that looked at talc and ovarian cancer came to different results than the retrospective case studies?

MS. PARFITT: Objection, form.

THE DEPONENT: Different conclusions or different results?

BY MR. HEGARTY:

Q. Different results.

A. Well, in the 2008 Gates' publication the result, the relative result is exactly the same as the result from the Terry pooled analysis

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of ten case-control studies, although the confidence interval is wider. Why is it wider? Because the number of subjects is so small that the confidence interval is wider.

The estimate of risk -- the best estimate of risk is still the point estimate, the 1.24, and that's exactly the same as Terry found.

So there are differences and there are similarities between those results.

Q. Is it your testimony that the conclusions reached in the prospective case-control studies are exactly the same as the conclusions reached in the case-control studies, the retrospective case-control studies?

MS. PARFITT: Objection, form.

THE DEPONENT: I was referring to one particular result from the Nurses' Health Study. The other result from the Nurses' Health Study, in the Gates 2010 paper and, as I've said before, I can't tell from the publications which of the two is a more valuable, informative result to rely on. Then that one is different from the consensus of the case-control studies.

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BY MR. HEGARTY:

Q. Which one?

A. Sorry, the Gates 2010 estimate of 1.06 with confidence interval from .89 to 1.28 that looks different to me than the, for example, the pooled results in the Terry analysis and all the other combined analyses, and various meta-analyses that have been carried out since the first one I guess in 1995 or '96. And I think Huncharek's the last one.

Q. The Houghton 2014 results also look different?

A. Yes.

Q. As well as the Gonzales 2016 results, correct?

A. Yes.

Q. Now, with regard to looking at dose response in the case control and the cohort studies, it is your opinion that you should exclude nonusers in that evaluation, correct?

A. It's not a simple thing. Many epidemiologist, in fact I would venture to say that most published, dose response relationship estimates in the literature include the nonexposed

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as part of the testing of statistical significance of the trend. There are reasons in favor and there are reasons against doing that. I tend to favor excluding the nonusers when that result -- when the trend result is juxtaposed with the ever never result from a study.

So what we have from a given study is the ever never result and the dose response pattern among the exposed, and those form a package of information that should be interpreted.

If -- failing that the unexposed group should be included in the analysis. If you don't take the ever never result into account when you're looking at the dose response then you should include the unexposed in the test for trend.

Q. The Terry paper on which you rely in your report does not include nonusers in the dose response analysis, correct?

A. Does not include nonusers?

Q. Correct.

A. I think it does. I think it presents results both using -- including nonusers and not including nonusers. That's my

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recollection but let me check that.
Q. In the abstract they report observing no significant trend in risk with increasing number of lifetime applications. That's based on excluding nonusers from the analysis, correct?
A. Can I answer your previous question first as to whether -- as to what they did?
Q. I think I changed my question.
A. Is it only the abstract that counts --
MS. PARFITT: No.
THE DEPONENT: -- for you?
BY MR. HEGARTY:
Q. My question -- let me restate the question. Let me withdraw that question and state another question.
In the abstract the authors say, "Among genital powder users we observed no significant trend P .17 in risk with increasing number of lifetime applications assessed in quartiles." That's what they said, correct?
MS. PARFITT: The question is whether they said that in the abstract only.

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BY MR. HEGARTY:
Q. Correct.
A. Yes, they said that in the abstract.
Q. That reference P .17 is excluding nonusers, correct?
A. Yes.
Q. And they don't report in the abstract any calculation that includes users, correct?
MS. PARFITT: In the abstract only.
THE DEPONENT: In the abstract.
BY MR. HEGARTY:
Q. Correct.
A. An abstract is a very, very concise extraction of information from an article. And it doesn't convey all the useful information in an article.
Q. In your report at page 36 you say:
"It is my view that the appropriate statistical test for trend is one that excludes the baseline, unexposed category. Since the baseline category is used for the overall binary relative risk it is preferable to keep the trend test independent of the test for overall relative risk."
That's what you said, right?
A. Correct. I would probably make a small amendment to make it clear that that assumes that the reader, or that the investigator is considering as a package the ever never result along with the trend test. It's together as a package that -- when they're used together as a package that I would argue that the trend test should be kept separate from the ever never result.
When somebody wants to disembody the trend test from considering the overall ever never result then the unexposed should be included in the trend test.
Q. Now, with regard to dose response you reported, with regard to looking at duration of use, no dose response across the studies that used that measurement?
MS. PARFITT: Objection, form.
THE DEPONENT: May I look at the table just to refresh my memory?
MS. PARFITT: Yes.

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BY MR. HEGARTY:
Q. With regard to the studies that use frequency as the measurement you also found no dose response, correct?
A. That's correct.
Q. With the studies that looked at frequency times duration, or cumulative number of applications you likewise found no dose response?
A. I'm sorry.
Q. You likewise found no dose response.
A. For which?
Q. For the cumulative exposure group of case-control studies.
MS. PARFITT: Objection, form.
THE DEPONENT: No, I disagree with that. I did find evidence of dose response.
BY MR. HEGARTY:
Q. Well, I'm not talking about evidence -- finding evidence of dose response. Did the data itself establish a dose response?
MR. ABNEY: Object to form.
THE DEPONENT: The data indicated that there was dose response and that the evidence for that was not statistically significant at the .05

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level, in conjunction with the fact that the overall ever never result was highly statistically significant.

BY MR. HEGARTY:

Q. When you say in your report that, "The Terry results are compatible with the presence of an underlying dose response", what does that mean?

A. It means that if there were a true dose response pattern the Terry results would fit, would be compatible with that hypothesis.

Q. If the number that Terry had calculated was statistically significant what would that interpretation be?

A. The interpretation there would be that if there truly was no dose response relationship the data that -- the data, as observed, would reject the hypothesis of no dose response.

Q. So the data as it is reported by -- strike that.

How would you phrase that same thing in the -- in the manner in which the data was reported by Terry?

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A. I would say that the data are compatible with the presence of an underlying dose response but they -- the hypothesis of no trend cannot be rejected.

Q. Got you, thanks.

You had made comments in -- or you made comments in your report with regard to the Schildkraut paper?

EXHIBIT NO. SIEMIATYCKI 22: Document titled "Association between Body Powder Use and Ovarian Cancer: The African American Cancer Epidemiology Study (AACES)" authored by Joellen M. Schildkraut et al.

MS. PARFITT: Is there a good time for a bio break?

MR. HEGARTY: Sure.

--- Break taken at 10:41 a.m.

--- Upon resuming at 10:58 a.m.

BY MR. HEGARTY:

Q. Doctor, when we broke we were getting ready to look at the Schildkraut paper, Exhibit 22, and you had made comments earlier in the deposition about Schildkraut. What criticism

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do you have of that paper? Do you have to read it again, Doctor?

A. It's been a few months since I read it so I just need to scan it at least to refresh my memory. I can't remember if in my report I explicitly addressed issues around it. If I did can you point me to it?

Q. Well, you made a comment a few minutes ago about Schildkraut being a poor study.

A. Did I?

Q. You must have some basis for making that comment.

A. Can someone read back to me what I said? Because I don't

MR. HEGARTY: Can you search?

THE COURT REPORTER: I don't have anything for that.

BY MR. HEGARTY:

Q. Let me ask you, do you think Schildkraut is a poor study?

A. Let me quickly refresh my memory.

Q. I'm sorry, let me restate that. You had said Gonzales was a poor study. Let's talk about Schildkraut, let me start over.

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A. I don't remember using that word "Schildkraut".

Q. Let me shift back gears. You had talked about Gonzales. What criticisms do you have of the Gonzales paper? I have a copy I'll mark it as Exhibit 23.

EXHIBIT NO. SIEMIATYCKI 23: Document titled "Douching, Talc Use, and Risk of Ovarian Cancer" authored by Nicole L. Gonzales et al.

BY MR. HEGARTY:

Q. It was Gonzales that you said was a poor study.

A. Did I use that term?

Q. I believe you did use that term.

A. Can you read back the sentence because I don't remember saying those words.

THE COURT REPORTER:

"ANSWER: The Gonzales 2016 paper by itself similarly, with the caveat that it's a particularly weak study because of very small numbers and some questionable data collection that's based on very fragile numbers."

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REPORTER'S CERTIFICATE

I, HELEN MARTINEAU, CSR, Certified Shorthand Reporter, certify;

That the foregoing proceedings were taken before me at the time and place therein set forth at which time the witness was put under oath by me;

That the testimony of the witness and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed;

That all notes were inserted as read;

That the foregoing is a true and accurate transcript of my shorthand notes so taken. Dated this 2nd day of January, 2017.

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PER: HELEN MARTINEAU

CERTIFIED SHORTHAND REPORTER

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ACKNOWLEDGMENT OF DEPONENT

I,______________________, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____

Jack Siemiatycki, Ph.D. DATE

Subscribed and sworn
to before me this
_____ day of ______________, 20____.
My commission expires:______________

____
Notary Public